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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,660	01/25/2002	Karlheinz Bortlik	88265-6773	4348

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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,660	BORTLIK ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 32-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-21 and 32-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response has been received and entered into the case. Claims 22 – 31 are canceled; claims 32 – 39 are added; claims 1 – 21 and 32 – 39 are pending and have been considered on the merits. All arguments have been fully considered.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed at the EPO on May 30, 2000. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter.

It is noted, however, that while the instant application is a CIP of PCT application EP01/06145, no copy of PCT document EP01/06145 has been submitted.

Claim Rejections - 35 USC § 112

Rejections under 35 U.S.C. 112, second paragraph, have been withdrawn due to amendment.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1 – 8, 10 – 16, 18 – 21, 32 – 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Potter (US 5855895 A).

Applicant claims a composition comprising at least one lipophillic bioactive compound (LBC) and a whey protein, wherein the protein is in an amount effective to increase the bioavailability of the bioactive compound. The LBC is obtained from plants selected from tomatoes, soya, green tea, green coffee bean, spices, grapes, cocoa, ginger or cereals; microorganisms of any bacterium, yeasts, or animal products selected from liver extract of milk fractions. The LBC is selected from carotenoids, polyphenols, lipophillic vitamins, flavonoids, isoflavones, curcuminoid, ceramide, proanthocyanidin, terpenoid, sterol, phytosterol, sterol ester, tocotrienol, squalene, retinoids, or mixtures thereof. Specifically, the LBC is a tomato extract, soybean extract or a mixture thereof; and the composition further comprises at least one of an

emulsifier, stabilizer, or other additive. The LBC is 0.05 – 50% of the composition, the whey protein is 5 – 90%; or the ratio of whey protein to LBC is 1:1 – 500:1. The composition is incorporated into an oral composition selected from a food stuff, supplement, cosmetic, or pharmaceutical preparation wherein the food stuff is a yogurt, drink, chocolate containing product, ice cream, cereal, coffee or animal food; and the supplement further comprises at least one of a sweetener, stabilizer, flavoring or colorant; and is a sugar coated tablet, pill, gelatin capsule, syrup, gel or cream. Applicant additionally claims a composition with 0.001 – 100% or 10 – 50% of the claimed composition, or a cosmetic comprising 10^-10 – 10% of the composition. Applicant additionally claims a composition comprising an LBC of a tomato oleoresin, a soybean extract or mixture thereof; and a whey protein in an amount effective to increase the bioavailability of the LBC.

Potter teaches pharmaceutical/supplement compositions comprising daidzein (LBC, isoflavone from soy), soy whey protein (abstract, col.6 line 60-63) and vitamins. The compositions are formulated into pills, capsules, powder or solutions and may contain carriers, binders, diluents, excipients (col.5 line 47-56), colorings and/or flavoring (col.6 line 7-8). The compositions may also be incorporated into foods, drinks, ice cream, or yogurt (col.6 line 13-30). Specifically, the compositions comprise 5 – 90% diadzein rich soy protein (or combined LBC and whey protein) (formulations).

Although the reference does not teach the source of the LBC, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When

the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113) Further, although Potter does not specifically teach oral or cosmetic compositions, the compositions are the same, as claimed.

Therefore the reference anticipates the claimed subject matter.

Applicant argues that while Potter teaches soy whey protein, the reference does not teach whey protein, which is derived from milk; that Potter does not teach the claimed ratio or amounts; that the lipophillic compound is not exogenous relative to the whey protein; and that Potter does not teach the lipophillic compound is more bioavailable when combined with the whey protein.

However, these arguments fail to persuade because Potter specifically teaches compositions comprising soy whey protein and daidzein (LBC). While Potter does not teach the whey protein is derived from milk, it is noted that the feature upon which applicant relies (specifically a milk derived whey protein) is not recited in the claims or defined by the specification. In addition, the compositions of Potter comprise 5 – 90% daidzien rich isolated proteins, wherein the proteins may be soy whey proteins. The amount would certainly comprise the claimed amounts of 0.05 – 50% LBC and 5 – 90% whey protein, as well as the 1:1 ratio as claimed by applicant. Regarding applicant's argument that the LBC is not exogenous to the whey protein, this limitation is also not recited in the rejected claims, and is not described as such in the specification. Finally, while Potter does not teach the LBC is more bioavailable,

discovery of an intrinsic feature in known composition does not change the composition or make the composition patentable, even though the function or use was not recognized.

Therefore, the claims are rejected over Potter.

4. Claims 1 – 10, 13 – 14, 16 and 18 - 21 stand rejected under 35 U.S.C. 102(b) as being anticipated by Schmitz (US 5643623 A).

Applicant claims a composition comprising at least one lipophillic bioactive compound (LBC) and a whey protein, wherein the protein is in an amount effective to increase the bioavailability of the bioactive compound. The LBC is obtained from plants selected from tomatoes, soya, green tea, green coffee bean, spices, grapes, cocoa, ginger or cereals; microorganisms of any bacterium, yeasts, or animal products selected from liver extract of milk fractions. The LBC is selected from carotenoids, polyphenols, lipophillic vitamins, flavonoids, isoflavones, curcuminoid, ceramide, proanthocyanidin, terpenoid, sterol, phytosterol, sterol ester, tocotrienol, squalene, retinoids, or mixtures thereof. Specifically, the LBC is a tomato extract, soybean extract or a mixture thereof. The composition is a powder, gel or liquid and further comprises vitamin C or tocopherol; or further comprises at least one of an emulsifier, stabilizer, or other additive; or is incorporated into an oral composition selected from a food stuff, supplement, cosmetic, or pharmaceutical preparation wherein the supplement further comprises at least one of a sweetener, stabilizer, flavoring or colorant; and is a sugar coated tablet, pill, gelatin capsule, syrup, gel or cream. Applicant claims a composition comprising 0.001 – 100% or 10 – 50% of the composition, or a cosmetic comprising 10^-10 – 10% of the composition.

Applicant additionally claims a composition comprising an LBC of a tomato oleoresin, a soybean extract or mixture thereof; and a whey protein in an amount effective to increase the bioavailability of the LBC.

Schmitz teaches food product compositions comprising lycopene, vitamin C, E, whey protein, flavors and colors (abstract, example 6) in forms of solid, gels or liquids (col.4 line 8-17).

Although the reference does not teach the source of the LBC, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113) Further, although Schmitz does not specifically teach oral or cosmetic compositions, the compositions are the same, as claimed.

Therefore the reference anticipates the claimed subject matter.

Applicant argues that Schmitz teaches an encapsulated, heterogenous composition, not a homogenous composition; and that Schmitz does not teach the whey protein enhances the bioavailability and/or function of the LBC, but as a carrier.

However these arguments fail to persuade because Schmitz specifically teaches compositions comprising the claimed ingredients in a single composition (example 6). It is also noted that the limitation which applicant relies upon (the composition is heterogeneous) is

neither recited in the claims, nor defined as such in the specification. Furthermore, while Schmitz does not recognize the intrinsic properties or function of the whey protein, such a function is inherent to the composition of Schmitz.

Therefore, the claims stand rejected over Schmitz.

5. Claims 1 – 7, 9 – 10 and 20 – 21 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Collins (US 6203805 B1).

Applicant claims a composition comprising at least one lipophillic bioactive compound (LBC) and a whey protein, wherein the protein is in an amount effective to increase the bioavailability of the bioactive compound. The LBC is obtained from plants selected from tomatoes, soya, green tea, green coffee bean, spices, grapes, cocoa, ginger or cereals; microorganisms of any bacterium, yeasts, or animal products selected from liver extract of milk fractions. The LBC is selected from carotenoids, polyphenols, lipophillic vitamins, flavonoids, isoflavones, curcuminoid, ceramide, proanthocyanidin, terpenoid, sterol, phytosterol, sterol ester, tocotrienol, squalene, retinoids, or mixtures thereof. The composition is a powder, gel or liquid and further comprises vitamin C or tocopherol; or further comprises at least one of an emulsifier, stabilizer, or other additive. The composition further comprises a compound active to the skin, is a cosmetic and is present at 10^-10 – 10%. Applicant additionally claims a composition comprising an LBC of a tomato oleoresin, a soybean extract or mixture thereof; and a whey protein in an amount effective to increase the bioavailability of the LBC.

Collins teaches topical, cosmetic and pharmaceutical compositions comprising whey protein, vitamin A, C and E (abstract, col.2 line 9-18). The compositions may further include other skin care ingredients, carriers, emulsifiers, stabilizers, preservatives or flavorings (col.5 line 35-65) and can be formed as liquids, emulsions, creams, gels and/or suspensions (col.5 line 23-30). Specifically, the whey protein is in amounts of 50 – 10,000ug/ml and the vitamin A is 1 – 100ug/ml (col.4 line 66 – col.5 line5).

Although the reference does not teach the source of the LBC, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Therefore the reference anticipates the claimed subject matter.

Applicant argues that Collins teaches a composition for topical use, not one where whey enhances the bioavailability of the LBC.

However these arguments fail to persuade because while Collins does not recognize the intrinsic properties or function of the whey protein, such a function is inherent to the composition of Collins.

Therefore, the claims stand rejected over Collins.

6. Claims 1 – 7, 11 – 14, 18 – 21, 32 – 33 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenberg.

Applicant claims a composition comprising at least one lipophillic bioactive compound (LBC) and a whey protein, wherein the protein is in an amount effective to increase the bioavailability of the bioactive compound. The LBC is obtained from plants selected from tomatoes, soya, green tea, green coffee bean, spices, grapes, cocoa, ginger or cereals; microorganisms of any bacterium, yeasts, or animal products selected from liver extract of milk fractions. The LBC is selected from carotenoids, polyphenols, lipophillic vitamins, flavonoids, isoflavones, curcuminoid, ceramide, proanthocyanidin, terpenoid, sterol, phytosterol, sterol ester, tocotrienol, squalene, retinoids, or mixtures thereof. The LBC is 0.05 – 50% of the composition and the whey protein is 5 – 90%; or the ratio of whey protein to LBC is 1:1 – 500:1. The composition is incorporated into an oral composition selected from a food stuff, supplement, cosmetic, or pharmaceutical preparation and is present at 0.001 – 100% or 10 – 50%; or is a cosmetic present at 10^-10 – 10%. Applicant additionally claims a composition comprising an LBC of a tomato oleoresin, a soybean extract or mixture thereof; and a whey protein in an amount effective to increase the bioavailability of the LBC.

Rosenberg teaches a composition comprising 10 – 75% vitamin A and 35 – 80% whey protein (example 6).

Although the reference does not teach the source of the LBC, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the

claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113) Further, although Rosenberg does not specifically teach oral or cosmetic compositions, the compositions are the same, as claimed.

Therefore the reference anticipates the claimed subject matter.

Applicant argues that Rosenberg does not teach that the composition is homogenous, but heterogeneous, and that Rosenberg does not teach the whey enhances the bioavailability of the LBC.

However these arguments fail to persuade because while Rosenberg does not recognize the intrinsic properties or function of the whey protein, such a function is inherent to the composition of Rosenberg.

Therefore, the claims stand rejected over Rosenberg.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1 – 16, 18 – 21 and 32 – 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Potter and Fujiwara.

Applicant claims a composition comprising at least one lipophillic bioactive compound (LBC) and a whey protein, wherein the protein is in an amount effective to increase the bioavailability of the bioactive compound. The LBC is obtained from plants selected from tomatoes, soya, green tea, green coffee bean, spices, grapes, cocoa, ginger or cereals; microorganisms of any bacterium, yeasts, or animal products selected from liver extract of milk fractions. The LBC is selected from carotenoids, polyphenols, lipophillic vitamins, flavonoids, isoflavones, curcuminoid, ceramide, proanthocyanidin, terpenoid, sterol, phytosterol, sterol ester, tocotrienol, squalene, retinoids, or mixtures thereof. Specifically, the LBC is a tomato extract, soybean extract or a mixture thereof; the composition is a powder, gel or liquid and further comprises vitamin C or tocopherol; or further comprises at least one of an emulsifier, stabilizer, or other additive; the LBC is 0.05 – 50% of the composition and the whey protein is 5 – 90%; or the ratio of whey protein to LBC is 1:1 – 500:1. The composition is incorporated into an oral

composition selected from a food stuff, supplement, cosmetic, or pharmaceutical preparation wherein the food stuff is a yogurt, drink, chocolate containing product, ice cream, cereal, coffee or animal food, and the supplement further comprises at least one of a sweetener, stabilizer, flavoring or colorant; and is a sugar coated tablet, pill, gelatin capsule, syrup, gel or cream. Applicant claims a composition comprising 0.001 – 100% or10 – 50% of the composition, or a cosmetic with 10^-10 – 10% of the composition. Applicant additionally claims a composition comprising an LBC of a tomato oleoresin, a soybean extract or mixture thereof; and a whey protein in an amount effective to increase the bioavailability of the LBC.

Potter teaches pharmaceutical/supplement compositions comprising daidzein (LBC, isoflavone from soy), soy whey protein (abstract, col.6 line 60-63) and vitamins. The compositions are formulated into pills, capsules, powder or solutions and may contain carriers, binders, diluents, excipients (col.5 line 47-56), colorings and/or flavoring (col.6 line 7-8). The compositions may also be incorporated into foods, drinks, ice cream, or yogurt (col.6 line 13-30). Specifically, the compositions comprise 5 – 90% diadzein rich soy protein (or combined LBC and whey protein) (formulations). Potter teaches the composition is effective to decrease LDL and increase HDL (abstract).

Fujiwara teaches a pharmaceutical comprising lycopene (tomato oleoresin/LBC) (abstract), soybean oil and vitamin E (tocopherol) (col.5). The composition is a gelatin capsule (abstract), tablet or powder and may further contain emulsifiers, stabilizers, coating agents, and/or solvents (col.3 line 47-55). Specifically, the composition comprises 30mg lycopene and 8mg soybean (col.5). Fujiwara teaches the composition is effective to decrease LDL and increase HDL (col.7 line32-43).

The references do not teach a composition comprising lycopene, soy extract and whey protein. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art to decrease LDL and increase HDL. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Potter and Fujiwara to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition effective to lower LDL and increase HDL. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Although the references do not teach the source of the LBC, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113) Further, although the references do not specifically teach oral or cosmetic compositions, the compositions are the same, as claimed.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that while LBC are known in the art in food or pharmaceutical compositions, the references do not teach including whey to increase the bioavailability of the LBC.

However, this argument fails to persuade because while the references do not specifically address the function of the whey, it is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In the instant case, one of ordinary skill in the art would have been motivated to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art to decrease LDL and increase HDL.

Therefore, the claims are rejected over Potter and Fujiwara.

10. Claims 1 – 16, 18 – 21 and 32 – 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitz.

Applicant claims a composition comprising at least one lipophillic bioactive compound (LBC) and a whey protein, wherein the protein is in an amount effective to increase the bioavailability of the bioactive compound. The LBC is obtained from plants selected from tomatoes, soya, green tea, green coffee bean, spices, grapes, cocoa, ginger or cereals; microorganisms of any bacterium, yeasts, or animal products selected from liver extract of milk fractions. The LBC is selected from carotenoids, polyphenols, lipophillic vitamins, flavonoids, isoflavones, curcuminoid, ceramide, proanthocyanidin, terpenoid, sterol, phytosterol, sterol ester, tocotrienol, squalene, retinoids, or mixtures thereof. Specifically, the LBC is a tomato extract,

soybean extract or a mixture thereof; the composition is a powder, gel or liquid and further comprises vitamin C or tocopherol; or further comprises at least one of an emulsifier, stabilizer, or other additive; the LBC is 0.05 – 50% of the composition and the whey protein is 5 – 90%; or the ratio of whey protein to LBC is 1:1 – 500:1. The composition is incorporated into an oral composition selected from a food stuff, supplement, cosmetic, or pharmaceutical preparation wherein the food stuff is a yogurt, drink, chocolate containing product, ice cream, cereal, coffee or animal food, and the supplement further comprises at least one of a sweetener, stabilizer, flavoring or colorant; and is a sugar coated tablet, pill, gelatin capsule, syrup, gel or cream. Applicant claims a composition comprising 0.001 – 100% or10 – 50% of the composition, or a cosmetic with 10^-10 – 10% of the composition. Applicant additionally claims a composition comprising an LBC of a tomato oleoresin, a soybean extract or mixture thereof; and a whey protein in an amount effective to increase the bioavailability of the LBC.

Schmitz teaches food product compositions comprising lycopene, vitamin C, E, whey protein, flavors and colors (abstract, example 6) in forms of solid, gels or liquids (col.4 line 8-17).

Schmitz does not teach the composition comprising the specific amounts and ratios of LBC and whey protein, or wherein the composition is in the claimed food forms. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such amounts and forms as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the various parameters of the compositions of Schmitz with a reasonable expectation for successfully obtaining a food product.

Although the reference does not teach the source of the LBC, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113) Further, although Schmitz does not specifically teach oral or cosmetic compositions, the compositions are the same, as claimed.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that Schmitz does not teach the claimed amounts or ratios; that the reference composition is heterogenous, not homogenous; that Schmitz does not teach the whey enhances the bioavailability of the LBC and that the whey is used as a carrier.

However, these arguments fail to persuade because as stated above, Schmitz specifically teaches compositions comprising the claimed ingredients in a single composition (example 6). It is also noted that the limitation which applicant relies upon (the composition is heterogeneous) is neither recited in the claims, nor defined as such in the specification. Furthermore, while Schmitz does not recognize the intrinsic properties or function of the whey protein, such a function is inherent to the composition of Schmitz. Regarding the amounts and ratios, it is noted that Schmitz teaches whey protein at 10 – 20% and the LBC at 0.1 – 1%, which overlaps the claimed amounts. Relative to the ratios, at the time of the claimed invention, it would have been

obvious to one of ordinary skill in the art to optimize the amounts and ratios or Schmitz as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts of effective ingredients of Schmitz with a reasonable expectation for successfully obtaining a health food composition.

Therefore the claims are rejected of Schmitz.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis; rad
March 8, 2004.

LEON B. LANKFORD, JR.
PRIMARY EXAMINER